IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED	:	
Plaintiff,	:	Civil Action No. 04-171-KAJ
v.	:	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED	:	**REDACTED VERSION**
Defendants.	:	

PLAINTIFF GLAXO'S MOTION FOR SUMMARY JUDGMENT DISMISSING DEFENDANTS' AFFIRMATIVE DEFENSES AND CORRESPONDING COUNTERCLAIM ALLEGING INEQUITABLE CONDUCT DURING THE PROSECUTION OF U.S. PATENT NO. 5,068,249

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Dated: June 30, 2006

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FEDERAL STATUTES

I. STATEMENT OF THE NATURE AND PROCEEDINGS OF THE CASE

Plaintiff Glaxo Group Limited ("Glaxo") patented a new and improved aqueous oral syrup formulation of ranitidine, an anti-ulcer medicine sold under the brand name Zantac® Syrup. On or about February 5, 2004, Glaxo received notice that defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (hereafter "defendant" or "Teva") submitted Abbreviated New Drug Application No. for generic Ranitidine Oral Solution USP, 15mg/mL (Teva's "ANDA Product") to the Food and Drug Administration ("FDA"). Defendant certified to the FDA that Glaxo's U.S. Patent No. 5,068,249 (the " '249 patent") is invalid, unenforceable and/or not infringed (but provided only an explanation as to its certification of non-infringement) and requested FDA approval prior to the '249 patent's expiration date. Glaxo filed its complaint in this action on March 18, 2004 alleging infringement of the claims (1-12) of the '249 patent. The '249 patent expires on November 26, 2008.

REDACTED

Discovery closed on May 26, 2006[1] with expert depositions concluding on June 8, 2006. Dispositive motions are ripe for consideration by the Court. Pursuant to Paragraph 10 of the Scheduling Order, Glaxo submits this opening brief and the accompanying Declarations of Oren D. Langer[2] and Bradley D. Anderson[3] in support of its motion to dismiss Teva USA's and Teva

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1 Except for a recent dispute between the parties concerning a document only recently identified by Teva on its privilege log and then subsequently produced upon request by counsel for Glaxo.

2 "Langer Decl." refers to the "Declaration of Oren D. Langer, in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief and Summary Judgment Motions on U.S. Patent No. 5,068,249" submitted herewith.

3 "Anderson Decl." refers to "Declaration of Bradley D. Anderson, Ph.D. in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief on U.S. Patent No. 5,068,249" submitted herewith.

Israel's affirmative defenses and corresponding counterclaims alleging inequitable conduct during the prosecution of the '249 patent.

II. SUMMARY OF ARGUMENT

Teva resorts to a frequently employed, but rarely warranted, strategy: attempting to mask their infringing conduct by alleging that the patent-in-suit is unenforceable due to the patentee's alleged inequitable conduct. The Federal Circuit has made clear its distaste for specious allegations of inequitable conduct:

> [T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps. They get anywhere with the accusation in but a small percentage of the cases, but such charges are not inconsequential on that account. They destroy the respect for one another's integrity, for being fellow members of an honorable profession, that used to make the bar a valuable help to the courts in making a sound disposition of their cases, and to sustain the good name of the bar itself. A patent litigant should be made to feel, therefore, that an unsupported charge of 'inequitable conduct in the Patent Office' is a negative contribution to the rightful administration of justice.

Burlington Indus. Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988). Teva's specious and unsupported charges of inequitable conduct are part of this "plague," and the Court should dismiss them. Teva cannot prove by clear and convincing evidence that Glaxo or any of its representatives committed inequitable conduct during prosecution of the '249 patent.

Teva's allegations are *identical* to those of Pharmadyne and are based on the *identical* evidence that was thoroughly considered and rejected by Judge Andre M. Davis in *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998) (the "*Pharmadyne* case"). In the *Pharmadyne* case, as in the present case, Pharmadyne alleged that Glaxo: "1) failed to tell the patent examiner that Tagamet contains ethanol; and 2) omitted and

misrepresented data in the Hempenstall Declaration." *Id.* at 305. The *Pharmadyne* court rejected these allegations after a thorough review of the '249 patent, the '249 patent prosecution history and the prior art, and after personally questioning Glaxo's witnesses and observing their demeanor at trial, including the inventor, Dr. David Long, and the author of the Hempenstall Declaration, Dr. John Hempenstall. The *Pharmadyne* court concluded that (1) the Tagamet solution was not material to the prosecution of the '249 patent, and (2) that neither Dr. Hempenstall nor any other Glaxo representative withheld or misrepresented stability data with the intent to mislead the PTO. *Id.* at 310-313. As to the allegation of withholding stability data from the PTO, the *Pharmadyne* court explained:

> I am persuaded that Dr. Hempenstall's recollection is reliable. There is no evidence that Dr. Hempenstall acted for any reason other than the reasons he stated. Pharmadyne essentially has asked the Court to find the requisite intent and materiality for inequitable conduct by Dr. Hempenstall in the exclusion of certain data from his declaration. Dr. Hempenstall excluded both favorable and unfavorable data and presented bona fide reasons for his decision to include and exclude data. Accordingly, I do not find inequitable conduct by Dr. Hempenstall.

Pharmadyne, 32 F. Supp. 2d at 313.

Discovery in this case is completed. Teva did not take any fact depositions and, therefore, does not have any new evidence to try to support the already-rejected inequitable conduct allegations. Teva rests its inequitable claims entirely on the same evidence proffered in the *Pharmadyne* case. The *Pharmadyne* court actively questioned the Glaxo witnesses on the stand, particularly Dr. Hempenstall, and satisfied itself that there was no inequitable conduct after thoroughly considering the witnesses' testimony and demeanor. Teva has nothing new to offer this Court that could in any way support its specious allegations of inequitable conduct. Accordingly, summary judgment in Glaxo's favor on Teva USA's Third Affirmative Defense

and corresponding counterclaim (Count III) and Teva Israel's Third and Fourth Affirmative Defenses is warranted. Fed. R. Civ. P. 56.

III. STATEMENT OF FACTS

A. The '249 Patented Invention

The '249 patent claims a pharmaceutical composition that is an aqueous formulation of ranitidine, or one of its physiologically acceptable salts, for oral administration. (Langer Decl., Ex. 1, Col. 1:40-53). Ranitidine, the active ingredient in Zantac® Syrup, controls gastric acid by selectively blocking the "H_2" (Histamine 2) receptor site on special cells (called "parietal cells") lining the stomach. This H_2 receptor site – when triggered with histamine – provokes a release of gastric acid into the stomach for digesting food, but excess stomach acid can cause ulcers and acid reflux. By selectively blocking the H_2 receptor site, Zantac® Syrup blocks histamine and prevents the release of gastric acid, thereby preventing and healing gastric ulcers and relieving acid reflux.

The '249 patent describes how the inventor, Dr. David Long, "surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of ethanol to the formulation." (*Id.* at Col. 1:40-44). The '249 patent goes on to explain that "[t]he amount of ethanol present in the formulation is such that the resulting formulation has the enhanced stability," and provides that "[p]referrably the amount of ethanol in the composition on a weight/volume basis of the complete formulation, is within the range 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v." (*Id.* at Col. 1:54-60).

B. The Invention Of The Pharmaceutical Composition Described And Claimed In The '249 Patent

1. Glaxo's Development Of The Original Zantac® Syrup Formulation Without Ethanol As A Stabilizer

In or about July 1976, Glaxo's scientists discovered and synthesized ranitidine. From the late 1970s to early 1980s, scientists in Glaxo's Pharmaceutical Research group experimented with different pharmaceutical formulations of ranitidine, including an aqueous oral syrup formulation.[4] *See Pharmadyne*, 32 F. Supp. at 277. (*See also* Long Tr.[5] 277-79, Langer Decl. Ex. 3). In November 1983, Glaxo submitted a Notice of Claimed Investigational Exemption for a New Drug ("IND") for Zantac® Syrup to the FDA. *See id.* (*See also* Glaxo IND at G007121, Langer Decl. Ex. 4). The original formulation for Zantac® Syrup, outlined in the IND, contained ranitidine hydrochloride and various excipients, including an antimicrobial preservative system to protect the syrup against bacterial contamination. *See id.* (*See also* Glaxo IND at G007138, Langer Decl. Ex. 4). The original Zantac® syrup formulation did not contain ethanol, but it demonstrated adequate chemical stability of ranitidine and also protected the syrup against the microorganisms listed in the United States Pharmacopeia ("USP"). *See id.* (*See also* Glaxo IND at G007138, G007193, Langer Decl. Ex. 4). After submission of the IND, further work in Glaxo's Pharmaceutical Research Laboratories revealed that, although the formulation was preserved against the microorganisms listed in the USP, the original formulation supported the growth of a waterborne bacterium known as *Pseudomonas cepacia*. *See id.* (*See also* Glaxo NDA at G006164, Langer Decl. Ex. 5; Long Tr. 279-81, Langer Decl., Ex. 3).

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[4] An aqueous oral solution or syrup formulation is particularly useful for young children, the elderly and anyone else in need of an anti-ulcer medicine who has trouble swallowing solid dosage forms (*i.e.*, tablets or capsules) of the drug.

[5] "Long Tr." refers to the trial testimony of Dr. David R. Long in the *Pharmadyne* case.

In or about July 1985, an in-use test on Glaxo's original non-ethanol formulation for Zantac® Syrup revealed a significant loss of one component of the preservative system due to *Pseudomonas cepacia* bacterial contamination. *See Pharmadyne*, 32 F. Supp. at 277. (*See also* Glaxo NDA at G006164, Langer Decl. Ex. 5; Long Tr. 280-81, Langer Decl., Ex. 3; Long 7/25/85 Memo at G026878, Langer Decl. Ex. 6). This contamination problem caused Glaxo to delay its product launch, which came to a "screeching halt." *See id.* (*See also* Long Tr. 279-80, Langer Decl., Ex. 3; Long 7/25/85 Memo at G026878, Langer Decl. Ex. 6). Dr. Long, Glaxo's Pharmaceutical Research Leader and the inventor of the '249 patent invention, had management responsibility during 1985 for development of Glaxo's Zantac® Syrup. (Long Tr. 265, 281-82, Langer Decl., Ex. 3).

2. Dr. David Long's Surprising Discovery That Adding Ethanol To An Aqueous Ranitidine Formulation For Oral Administration Enhances Ranitidine Stability

Dr. Long devised a strategy for overcoming the bacterial contamination problem in the original formulation for Zantac® Syrup, which ultimately led to his surprising discovery that adding ethanol to an aqueous ranitidine formulation for oral administration enhances ranitidine stability. *See Pharmadyne*, 32 F. Supp. 2d at 278. (*See also* Long Tr. 281-84, 404-12, Langer Decl. Ex. 3). His strategy called for an assessment of various syrup formulations and challenging those formulations with *Pseudomonas cepacia*. *See id.* (*See also* Long Tr. 284, 404-12, Langer Decl., Ex. 3; Long Notes at G026881-82, Langer Decl., Ex. 7). In or about August 1985, Dr. Long decided to assess a syrup formulation with 5% (weight/volume "(w/v)") ethanol because ethanol was a known and effective antimicrobial preservative for aqueous pharmaceutical products. *See id.* (*See also* Long Tr. 410-12, 417-18, Langer Decl. Ex. 3; Long Notes at G026881-82, Langer Decl., Ex. 7; Lab Notebook P590 at G026729, G026742, Langer

Decl., Ex. 8). Dr. Long hoped that the addition of ethanol would cure the bacterial contamination problem without negatively affecting the chemical stability of ranitidine in the formulation. *See id.* at 279. (*See also* Long Tr. 287, 425, Langer Decl., Ex. 3). Based on the results of testing performed at Dr. Long's direction, Dr. Long preliminarily concluded that the 5% (w/v) ethanol formulation solved the problem of *Pseudomonas cepacia* contamination. *See id.* (*See also* Long Tr. 411-12, 417-18, Langer Decl., Ex. 3; Long 8/28/85 Letter at G026879, Langer Decl., Ex. 9; Lab Notebook P590 at G026742, Langer Decl., Ex. 8).

In or about October 1985, Dr. Long and his team concluded that 7.5% (w/v) ethanol would be included in the Zantac® Syrup formulation to ensure that a minimum of 5% (w/v) ethanol would remain in the product formulation throughout its assigned shelf-life to preserve it against *Pseudomonas cepacia* contamination. *See Pharmadyne*, 32 F. Supp. at 279. (*See also* Long Tr. 421-22, Langer Decl., Ex. 3; Lab Notebook P590 at G026807, Langer Decl., Ex. 8). The 7.5% (w/v) ethanol formulation for Zantac® Syrup was put on stability review to determine whether the ranitidine in the new formulation was, in fact, chemically stable throughout the assigned 18-month shelf-life for Zantac® Syrup. *See id.* (*See also* Long Tr. 421-22, Langer Decl., Ex. 3; Lab Notebook P590 at G026865-71, Langer Decl., Ex. 8). Later on, after Glaxo had obtained stability study data for the reformulated Zantac® Syrup containing 7.5% ethanol, analysis of the stability study data surprisingly and unexpectedly indicated that ethanol actually *enhanced* the chemical stability of ranitidine in Zantac® Syrup. *See id.* at 277, 279. (*See also* Long Tr. 424-25, Langer Decl., Ex. 3; Lab Notebook P590 at G026871-73, Langer Decl., Ex. 8). Based on this surprising and unexpected discovery, Glaxo filed British Patent Application No. GB 8629781 on December 12, 1986 in the name of Dr. Long. *See id.* at 279. (*See also* '249 File History at G000249-57, Langer Decl., Ex. 10).

On December 11, 1987, Glaxo filed a corresponding patent application in the United States. *See id.* (*See also* '249 File History at G000249-57, Langer Decl., Ex. 10). Glaxo claimed foreign priority based on its earlier-filed British Patent Application No. GB 8629781. *See id.* (*See also* '249 File History at G000249-57, Langer Decl., Ex. 10). Glaxo thereafter filed two continuation applications which led to the issuance of the '249 patent on November 26, 1991.

C. The Prosecution History Of The '249 Patent

The '249 patent has a foreign application priority date of December 12, 1986, based on British Patent Application No. GB 8629781. (Langer Decl., Ex. 1, cover page). U.S. Application No. 131,442 was filed on December 11, 1987, within one year of the foreign application priority date. (*Id.*). U.S. Application No. 131,442 was later abandoned and a continuation application, U.S. Application No. 344,620, was filed on April 28, 1989. (*Id.*). U.S. Application No. 344,620 was later abandoned and a file wrapper continuation application, U.S. Application No. 494,804, was filed on March 14, 1990. (*Id.*). U.S. Application No. 494,804 issued as the '249 patent on November 26, 1991. (*Id.*).

1. U.S. Application No. 131,442, Filed On December 11, 1987, And Continuation Application No. 344,620, Filed On April 27, 1989

The examination of U.S. Application No. 131,442 and Continuation Application No. 344,620 are substantively quite similar and will be treated together for convenience. Both applications contained the same fourteen (14) original claims. ('249 File History at G000243-44, G000120-21, Langer Decl., Ex. 10). Independent claim 1 was originally filed as follows:

> 1. A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiological acceptable salts thereof, said formulation also containing ethanol.

(*Id.* at G000243, G000120).

In Office Actions dated May 5, 1988 and June 28, 1989, U.S. Patent Office Examiner Friedman rejected claim 1 and other claims of the applications as indefinite and non-enabled under 35 U.S.C. § 112 and as being unpatentable under 35 U.S.C. § 103 over two Chemical Abstracts cited by the Examiner. (*Id.* at G000264-65, G000131-33). Examiner Friedman stated that the claims were not enabled under 35 U.S.C. § 112 because "[a]ll claims should recite amounts for all ingredients." (*Id.* at G000264, G000131). As to the Examiner's rejection under 35 U.S.C. § 103, he stated that the two Chemical Abstracts taught "the cojoined use of use of [sic] ranitidine and an alcohol (ethanol)." (*Id.* at G000132; *see also* G000265).

Applicant filed responsive Amendments on November 7, 1988 and October 30, 1989, respectively. Applicant amended Claim 1 as follows:

> 1. (Amended) A pharmaceutical composition which is an aqueous formulation <u>for oral administration</u> of ranitidine and/or one or more physiological acceptable salts thereof, said formulation also containing <u>a stabilizing effective amount of</u> ethanol <u>and said composition having a pH in the range of 6.5 to 7.5</u>.

(10/30/89 Amendment, '249 File History at G000139, Langer Decl., Ex. 10; *see also* G000267). Applicant explained to the Examiner that "the amount of ethanol present has been functionally defined. . . . The expression 'also containing ethanol' has been modified to specify that the amount of ethanol contained in the composition is a stabilizing amount of ethanol and this amendment is fully supported by applicant's specification at page 2, lines 4 and 5 ['249 patent, Col. 1:54-56]." (*Id.* at G000267-68, G000140). As to the two Chemical Abstracts cited by the Examiner, applicant explained that "there is no teaching whatever that the stability of ranitidine or its salts as an aqueous formulation for oral administration is enhanced by the presence of ethanol and no suggestion that ethanol should be included in pharmaceutical formulations containing ranitidine as presently claimed." (*Id.* at G000142; *see also* G000269).

Applicant further emphasized the importance of stabilizing the active ingredient in a pharmaceutical formulation for oral administration:

> Applicant wishes to reiterate that the stability of a pharmaceutical formulation for oral administration is the most important factor and enhancing the stability of the active ingredient of such formulations is always an objective. Thus, in the development of any pharmaceutical formulation, it is necessary to ensure that the drug substance is stable within the formulation and this is necessary for two reasons. Firstly, the drug substance must be stable in order to ensure that the patient is receiving the correct dosage of the drug. Secondly, it is important to ensure that the patient is not receiving significant amounts of breakdown products arising from the degradation of the drug substance in the formulation. This second point is particularly important since it is not always possible to identify fully all of the breakdown products that may occur. Consequently, the chronic toxicity of all the various compounds arising from the breakdown of the drug substance cannot be determined.
>
> In practice, degradation of the drug substance within a formulation usually occurs upon storage and is often dependent upon a number of factors including temperature and time of storage. Any improvement that can be made in enhancing the stability of the drug substance can only benefit the patient since it ensures more accurate dosage and the intake of less breakdown products. In addition, enhancement of the stability of the drug substances also benefit from the economic point of view in that it increases the effective shelf life of the product.

(10/30/89 Amendment, '249 File History at G000143-44, Langer Decl., Ex. 10). On November 29, 1988 and on November 14, 1989, respectively, Examiner Friedman issued Office Actions maintaining the rejections under 35 U.S.C. § 112, questioning the use of the word "also" in claim 1 and indicating that the amount of ranitidine was still not adequately defined. (*Id.* at G000272, G000161). The Examiner also maintained his rejection of the claims over the two Chemical Abstracts under 35 U.S.C. § 103. (*Id.*). The Examiner further stated that "[a]s for the allegation of enhanced stability, it has not been demonstrated for the compositions urged as contrasted with any of other pH parameters." (*Id.* at G000161).

2. File Wrapper Continuation Application No. 494,804 Filed On March 14, 1990

On March 14, 1990, applicant filed file wrapper continuation application no. 494,804. (*Id.* at G000164). The file wrapper continuation application incorporated the amendments that had been made during prosecution of U.S. Application No. 344,620. In an Office Action dated May 4, 1990, Examiner Friedman repeated his earlier rejections under 35 U.S.C. § 112 and § 103. (*Id.* at G000170-71).

In an Amendment filed on October 31, 1990, claim 1 was further amended as follows:

> 1. A pharmaceutical composition which is an aqueous formulation for oral administration [of][6] an effective amount of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation ~~also containing~~ comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

('249 File History at G000173, G000139, Langer Decl., Ex. 10). This became the final form of claim 1 in the later-issued '249 patent. Applicant explained that "Claim 1 has been amended to indicate that the ranitidine present is present in an effective amount and to delete the objected to terminology 'also containing'." (*Id.* at G000174). As to the two Chemical Abstracts cited by the Examiner, applicant again explained that: "[T]here is no teaching whatever that the stability of ranitidine or its salts as an aqueous formulation for oral administration is enhanced by the presence of ethanol and no suggestion that ethanol should be included in pharmaceutical formulations containing ranitidine as presently claimed." (*Id.* at G000175). Using language nearly identical to that used in the October 30, 1989 Amendment (quoted above at p. 10),

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[6] The word "of" was later added by an Examiner's Amendment dated May 30, 1991 in conjunction with the Examiner's June 3, 1991 Notice of Allowability. ('249 File History at G000212-12, Langer Decl. Ex. 10).

applicant reiterated the importance of stabilizing ranitidine in a pharmaceutical formulation for oral administration, explaining, *inter alia*:

> "[E]nhancing the stability of the active ingredients of such formulations [for oral administration] is always an objective. . . . Any improvement that can be made in enhancing the stability of the drug substance can only benefit the patient since it ensures more accurate dosage and the intake of less breakdown products. In addition, enhancement of the stability of the drug substance also benefits from the economic point of view in that it increases the effective shelf life of the product. There is not even the most remote suggestion of this in the prior art of record."

(*Id.* at G000176). Applicant also stated that: "Applicant is in the process of preparing a Declaration to substantiate the unexpected effect of ethanol in enhancing the stability of ranitidine in aqueous oral formulations." (*Id.* at G000177).

On January 22, 1991, new Examiners Waddell and Gardner issued an Office Action stating that: "[R]ejections presented by Examiner Friedman in the Office Action dated 5/4/90 are deemed to be overcome by the amendment filed on 10/31/90." ('249 File History at G000199, Langer Decl., Ex. 10). The Examiners went on to explain: "However, new rejections must now be presented as a result of the additional documents which were filed on 1/10/91." (*Id.*). Curiously, the Examiners rejected the claims "under 35 U.S.C. § 102(a) and (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Padfield et al. (GB 2142820)" (*Id.* at G000200), a prior art reference that Glaxo had described in the background portion of the '249 patent application and which had been disclosed by Glaxo to the Patent Office at the very beginning of the prosecution. (*See* April 8, 1988 Information Disclosure Statement, '249 File History at G000258-261, Langer Dec. Ex. 10). The Examiners stated:

> Padfield et al. [the '820 patent] teach the enhanced stability of aqueous compositions of ranitidine formulated at a pH in the range of 6.5 to 7.5. The applicant's invention is directed to aqueous compositions of ranitidine formulated at a pH in the rage [sic

> range] of 6.5 to 7.5 and with the addition of ethanol. It has not been demonstrated in the record, by means of experimental data, that the applicant's invention produces any unexpected results. The disclosure, as presented, is insufficient to overcome the prior art without the aid of experimental data to show a definite improvement over the GB patent [the '820 patent]. Since the GB patent [the '820 patent] teaches an aqueous composition of ranitidine, it is considered well within the state of the art to choose ethanol as an additive which would be considered pharmaceutically acceptable when formulating this composition. Absent evidence to the contrary, the addition of ethanol is considered merely to be a choice among known conventional excipients.

(*Id.* at G000200).

On May 10, 1991, applicant filed a Request for Reconsideration and enclosed a Declaration of Dr. John Hempenstall (the "Hempenstall Declaration"). (*Id.* at G000204-211). Applicant explained that the Hempenstall Declaration:

> [P]rovides convincing evidence that the compositions of the present invention show a quite unexpected advantage over the teachings of GB-A-2142820 [the '820 patent] in terms of the stability of the ranitidine in the composition. In this connection, it is noted that the liquid formulation without ethanol which is used in the Declaration for purposes of comparison is the same as the formulation of Example 3 of Padfield et al. [the '820 patent]. Accordingly, the Declaration presents a direct comparison between a composition according to the present invention and a composition according to the prior art . . . Applicant acknowledges that ethanol has previously been used in pharmaceutical compositions. However, the purpose for which ethanol has been included has been either as a solvent or as a preservative against bacterial contamination. There was, however, no reason to suppose that either of these functions of ethanol would have had any beneficial effects in terms of limiting the degradation of ranitidine in aqueous formulations thereof.

(*Id.* at G000205).

In the Hempenstall Declaration, Dr. Hempenstall explained:

> In the development of any pharmaceutical presentation it is necessary to ensure that the drug substance is stable within the formulation for as long a time period as is practical, so that the

> patient is receiving the correct dosage and also that he or she is not receiving significant amounts of breakdown products arising from the degradation of the drug substance in the formulation. This latter point is particularly important since it is not always possible to fully identify all the breakdown products that can occur and consequently one cannot determine the chronic toxicity of all the various compounds arising from the breakdown of the drug substance.

(*Id.* at G000208-09, ¶ 4). Dr. Hempenstall went on to explain: "In my laboratory it was found that for an aqueous based ranitidine formulation, a significant and surprising enhancement in the stability of ranitidine is achieved by the addition of ethanol to the formulation." ('249 File History at G000209, ¶ 5, Langer Decl., Ex. 10). Stability studies were analyzed by Dr. Hempenstall comparing (i) aqueous ranitidine formulations for oral administration containing 7.5% ethanol in the formulation, to (ii) aqueous ranitidine formulations for oral administration without ethanol in the formulation. (*Id.* at G000209, ¶ 6).

Dr. Hempenstall explained that: "[T]he acceptable shelf life for an aqueous formulation containing ranitidine hydrochloride is considered to be the time at which no more than 5% of the ranitidine present in the formulation has degraded. Accordingly, the figure determined from the stability studies was the time (in months) for 5% ranitidine loss calculated as the lower 95% confidence limit." (*Id.* at G000210, ¶ 6). Dr. Hempenstall concluded that "the formulation with ethanol has an average shelf life at 30°C of 19 months compared with 13 months when ethanol is excluded from the formulation. This is a highly significant and valuable improvement." (*Id.* at G000211, ¶ 6). Dr. Hempenstall further concluded that "ethanol has a beneficial effect upon the stability of ranitidine in aqueous based formulations and furthermore I am not aware of any teaching in the art that would lead me to expect such an effect." (*Id.* at G000211, ¶ 7).

Before Dr. Hempenstall prepared the Hempenstall Declaration, he asked Glaxo's Statistics Department for statistical analyses of the comparative studies that Glaxo had conducted

on ethanol and non-ethanol formulations in the United States and the United Kingdom. *See Pharmadyne*, 32 F. Supp. 2d at 312. (*See also* Hempenstall Tr.[7] 4245-49, Langer Decl., Ex. 16; May 15, 1990 Elahi Report at G026932-950, Langer Decl. Ex. 17). His purpose was to determine whether the addition of ethanol to an aqueous formulation for oral administration containing the active ingredient ranitidine resulted in a statistically significant improvement in shelf-life. *See id.* (*See also* Hempenstall Tr. 4245-49, Langer Decl., Ex. 16; May 15, 1990 Elahi Report at G026932-950, Langer Decl. Ex. 17). Dr. Hempenstall used these statistical analyses to prepare the Hempenstall Declaration. *See id.* (*See also* Hempenstall Tr. 4259-60, Langer Decl., Ex. 16). Dr. Hempenstall used his experience and sound professional judgment in deciding what data was appropriate, fair, and sufficient and what data was inappropriate, unreliable, or unnecessary to include in the Hempenstall Declaration. *See id.* at 312-313. (*See also* Hempenstall Tr. 4249-61, 4280, 4294, 4334-4339, Langer Decl., Ex. 16; '249 File History at G000208-11, Langer Decl. Ex. 10; Anderson Rebuttal Rpt.[8] ¶¶ 37-39).

Supervisory Patent Examiner Waddell issued a Notice of Allowability on June 3, 1991 in response to the May 10, 1991 Request for Reconsideration and the Hempenstall Declaration. ('249 File History at G000212, Langer Decl., Ex. 10). The final language of claim 1, approved by the Examiners, and showing the amendments made during prosecution, reads as follows (underline denotes additions and strike-through denotes deletions):

> 1. A pharmaceutical composition which is an aqueous formulation <u>for oral administration</u> <u>of</u> <u>an effective amount</u> of ranitidine and/or one or more physiologically acceptable salts thereof, said

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[7] "Hempenstall Tr." refers to the trial testimony of Dr. John M. Hempenstall in the *Pharmadyne* case.

[8] "Anderson Rebuttal Rpt." refers to "Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Rebuttal Expert Witness Report" attached as Exhibit B to the Anderson Decl.

formulation ~~also containing~~ comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

(*Id.* at G000213).

IV. ARGUMENT

A. Statement Of Applicable Law

1. An Inequitable Conduct Defense May Be Dismissed On Summary Judgment

"Summary judgment is as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). Indeed, the Federal Circuit encourages the proper use of Rule 56, having stated that, "[w]here no issue of material fact is present . . . courts *should not hesitate* to avoid an unnecessary trial by proceeding under Fed.R.Civ.P. 56 . . . ." *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 778-79 (Fed. Cir. 1983) (emphasis added); *see also Barmag*, 731 F.2d at 835 ("the court *should utilize* the salutary procedure of Fed.R.Civ.P. 56 *to avoid unnecessary expense* to the parties and wasteful utilization of . . . judicial resources.") (emphasis added). By virtue of Rule 56, summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1339 (Fed. Cir. 2006).

A court may resolve and dispose of allegations of inequitable conduct on summary judgment. *Sightsound.com Inc. v. N2K, Inc.*, 391 F. Supp. 2d 321, 357-367 (W.D. Pa. 2003). "When evaluating a motion for summary judgment, the court views the record evidence through the prism of the evidentiary standard of proof that would pertain at a trial on the merits." *Eli*

Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed. Cir. 2001) (*citing Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 252 (1986)). Where, as here, the clear and convincing standard is applicable, a nonmovant cannot survive summary judgment by presenting evidence that only satisfies the preponderance of the evidence standard. *See Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 255-56 (1986); *Braun, Inc. v. Dynamics Corp. of America*, 975 F.2d 815, 822 (Fed. Cir. 1992) (explaining that for a claim of inequitable conduct, both intent and materiality must be proven by clear and convincing evidence). The clear and convincing standard is met when "[the plaintiff] [places] in the ultimate factfinder an abiding conviction that the truth of its factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

At the summary judgment phase, the moving party seeking to dismiss an inequitable conduct defense must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable fact finder (in this case, the Court) could find the patent unenforceable. *See, e.g.*, *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1126, 1130 (E.D. Cal. 2002); *see also Eli Lilly & Co.*, 251 F.3d at 962 ("[A] moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent."). Summary judgment thus may be granted to a patentee accused of inequitable conduct "when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant cannot prevail." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998); *see also Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002) (affirming trial court's grant of summary judgment dismissing inequitable conduct defense); *Fuji Photo Film Co., Ltd. v. Jazz Photo Corp., Inc.*, 173 F. Supp.

2d 268 (D.N.J. 2001) (granting partial summary judgment on inequitable conduct defense); *AT&T Corp. v. Microsoft Corp.*, No. 01 Civ. 4872 WHP, 2004 WL 232725 (S.D.N.Y. Feb. 9, 2004) (same) (attached hereto as Ex. A).

2. To Prevail On An Inequitable Conduct Charge, The Accuser Must Put Forth Clear And Convincing Evidence That The Patentee Intentionally Misled The Patent Office Regarding Information Material To Patentability

"Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Board of Educ. v. American Bioscience, Inc.*, 333 F.3d 1330, 1343 (Fed. Cir. 2003) (citations omitted). Before the court can take the drastic step of rendering a patent unenforceable, it must first determine that the patentee's conduct meets a threshold level of materiality and that the evidence demonstrates a threshold level of intent to mislead the patent office. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Only after threshold findings of materiality and intent are established may the court "weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred." *Id.* (citations omitted).

To prove inequitable conduct for a material omission by clear and convincing evidence, the accuser must show:

> (1) prior art that was material; (2) knowledge chargeable to an applicant of that prior art and its materiality; and (3) failure of the applicant to disclose the art resulting from an intent to mislead the PTO.

Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999) (citations omitted). The patentee may rebut such allegations with proof that the prior art was not material,

or, if it was material, that the patentee was unaware of it or its materiality, or that the nondisclosure was not the result of an intent to mislead the PTO. *See id.*

a. Information Material To Patentability

Under 37 C.F.R. § 1.56, a patent applicant has a duty of candor and good faith in dealing with the PTO, which includes an obligation to disclose information to the PTO that is known by the applicant to be material to patentability. Under that rule, information is material if there is "substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (1991)[9]; *see, e.g., Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991). "An otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed." *Elk Corp.*, 168 F.3d at 31 (citations omitted); *see also Halliburton*, 925 F.2d at 1440. "[A]n applicant for patent is under *no* obligation to disclose all pertinent prior art or other pertinent information of which he is aware," because such a requirement would cut too broadly and would vitiate the materiality requirement. *American Hoist & Derrick Co. v. Sowa & Sons., Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (citations omitted) (emphasis added).

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[9] 37 C.F.R. § 1.56 has since been amended and the Federal Circuit has "not yet determined whether the new Rule 56 is the same as the 'reasonable examiner' standard of the old Rule 56 . . . ." *Digital Control Inc. v. The Charles Machine Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006). The Federal Circuit has expressly stated that "the PTO's recent adoption of an arguably narrower standard of materiality [the new Rule 56], does not supplant or replace our case law. That is, if a misstatement or omission is material under the new *Rule 56* standard, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard or under the older three tests, it is also material." *Id.* at 1316. Because the present litigation involves a patent that was prosecuted entirely pre-1992, the old Rule 56 standard of materiality under 37 C.F.R. § 1.56(b) should apply.

b. Specific Intent To Mislead The PTO

Even assuming that the threshold level of materiality has been met, the Court still must determine whether there exists clear and convincing evidence of an intent to deceive the PTO. *See Upjohn Co. v. Mova Pharma. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000) ("'[M]ateriality does not presume intent, which is a *separate and essential* component of inequitable conduct.'") (*quoting Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990)) (emphasis added); *see also Halliburton Co.*, 925 F.2d at 1442 ("[T]he materiality of an undisclosed reference does not presume an intent to deceive."). "Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable conduct is required." *Molins*, 48 F.3d at 1181.

A court may not infer intent based on a finding that the patentee did not disclose information; "there must be a factual basis for a finding of deceptive intent." *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996) (citations omitted); *see also FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 (Fed. Cir. 1987) (explaining that an inference of specific intent can be drawn from a fact, but intent cannot be established by "drawing an inference on an inference on an inference"). Even a finding of gross negligence does not justify an inference of intent to deceive; rather, conduct *in toto* must be sufficient to require a finding of deceitful intent in view of all the circumstances. *See Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). Indeed, "alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to accomplish an act that the applicant ought not to have performed, *viz.*, misleading or deceiving the USPTO." *Molins*, 48 F.3d at 1181 (emphasis added).

c. The Balancing By The Court

If, but only if, the Court determines that defendant has presented clear and convincing evidence establishing the threshold levels of materiality and intent, then the court must determine, in its discretion, whether inequitable conduct exists. *See Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001). In making this determination, the court conducts a balancing test between the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other. *See id.* (citations omitted). Ultimately, the court must determine whether, in view of all the circumstances, the applicant's conduct is so culpable that the patent should be held unenforceable. *See American Bioscience,* 333 F.3d at 1343.

B. Teva Cannot Prove By Clear And Convincing Evidence That Glaxo And/Or Its Representatives Committed Inequitable Conduct During The Prosecution Of The '249 Patent

Teva sets forth the bases for its inequitable conduct charge in its Answers and Counterclaims and in its Responses and Amended Responses to Glaxo's Interrogatories. In Teva's Responses to Glaxo's Interrogatories, Teva states the following:

> [U]pon information and belief, the Applicant of the '249 patent and/or his agents knowingly withheld knowledge of a prior Tagamet solution containing ethanol from the Patent Office. This solution is more relevant in some respects than the prior art cited during the prosecution of the '249 patent. Upon information and belief, the Applicant and/or his agents did so with the intent to mislead the Patent Office.
>
> Upon information and belief, the Applicant and/or his agents (including Dr. Hempenstall) also knowingly withheld stability data from the Patent Office during the prosecution of the '249 patent. Upon information and belief, the withheld data was highly material to the patentability of the '249 patent, and the Patent Examiner should have been allowed to review this data to determine for himself whether Dr. Hempenstall's claims were accurate. Upon information and belief, the Applicant and/or his

> agents (including Dr. Hempenstall) did so with the intent to mislead the Patent Office. As a result of the Applicant's and/or his agents' inequitable conduct during the prosecution of the '249 patent, all the claims of the '249 patent are unenforceable.

(Teva USA's Answer to Interrogatory No. 8 at p. 13, Langer Decl., Ex. 13; Teva Israel's Answer to Interrogatory No. 5 at pp. 10-11, Langer Decl., Ex. 14; *see also* D.I. 5, Teva USA's Answer and Counterclaims, Third Affirmative Defense (¶¶ 3-8), Count III (¶¶ 14-19); D.I. 20, Teva Israel's Second Answer, Third and Fourth Affirmative Defenses (¶¶ 3-8)). Teva's allegations are vague, specious, unsupportable and, in short, identical to the allegations made by Pharmadyne and rejected by Judge Davis in the *Pharmadyne* case – that is, that Glaxo: "1) failed to tell the patent examiner that Tagamet contains ethanol; and 2) omitted and misrepresented data in the Hempenstall Declaration." *Pharmadyne*, 32 F. Supp. 2d at 305. Teva, moreover, did not take any fact depositions and does not have any new evidence to try to support its claims. Discovery in this case is completed. Teva is left to rest its claims solely on the same testimony and evidence already considered and rejected by the court in the *Pharmadyne* case. For the reasons explained further below, summary judgment dismissing Teva's claims is appropriate.[10]

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[10] Not only is Teva unable to prove by clear and convincing evidence its claims that the '249 patent is unenforceable due to inequitable conduct, Teva has not even pled its claims with particularity, as required under Rule 9(b), Fed. R. Civ. P. *See Ferguson Beauregard/Logic Controls v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). Teva must plead specifically what statements were made and in what context, when they were made, who made them, and the manner in which the statements were misleading. *See Agere Systems Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 734 (D. Del. 2002) ("[I]n pleading an inequitable conduct claim, a party cannot merely rely on vague allegations that broadly recite the elements of fraud, but instead must either specify the time, place, and content of any alleged misrepresentations made to the PTO . . . ."). Teva has pled none of this with specificity – another reason dismissing Teva's claims is appropriate. (D.I. 5, Teva USA's Answer and Counterclaims, Third Affirmative Defense (¶¶ 3-8), Count III (¶¶ 14-19); D.I. 20, Teva Israel's Second Answer, Third and Fourth Affirmative Defenses (¶¶ 3-8)).

1. Teva Cannot Prove By Clear And Convincing Evidence That Glaxo Knowingly Withheld Knowledge Of A Prior Tagamet Solution Containing Ethanol With The Intent To Mislead The PTO

Teva alleges that Glaxo and/or its agents committed inequitable conduct by "knowingly withh[olding] knowledge of a prior Tagamet solution containing ethanol from the [PTO]." The *Pharmadyne* court rejected this same allegation[11], concluding that the Tagamet solution was not material to the prosecution of the '249 patent. The *Pharmadyne* court explained:

> Although both Tagamet and ranitidine hydrochloride are used to treat ulcer-type ailments, there clearly are chemical differences between the two. As I noted previously, Tagamet's active ingredient is cimetidine, not ranitidine hydrochloride. Cimetidine is a guanadine, not an enamine like ranitidine hydrochloride. Based on Dr. Bernstein's testimony explaining that chemical compounds in the same family or group usually react similarly, and the fact that cimetidine and ranitidine hydrochloride are not the same type of compound, it is difficult to see the connection between the Tagamet reference and the claims of the '249 patent. Pharmadyne has produced little evidence establishing a nexus between the two other than the fact that they are H_2-antagonist drugs. Accordingly, materiality has not been demonstrated.

32 F. Supp. 2d at 310. The *Pharmadyne* court went on to explain that even if the Tagamet solution was relevant, it was cumulative of other prior art that was provided by Glaxo and considered by the Examiner and, thus, not material. Specifically, the *Pharmadyne* court explained:

> Even if Pharmadyne had otherwise established the materiality of the Tagamet reference, the reference is cumulative

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[11] In the *Pharmadyne* case, Pharmadyne alleged that "it was scientifically misleading for Glaxo not to have disclosed to the PTO that Tagamet contained approximately 3% ethanol." *Pharmadyne*, 32 F. Supp. 2d at 310. Pharmadyne alleged that this was "relevant information because Tagamet performs a pharmaceutical function similar to ranitidine and Dr. Long proceeded to use ethanol in the ranitidine solution because he knew that Tagamet contained ethanol." *Id.*

> and, therefore, not material. The patent examiner rejected the '249 patent application numerous times on the ground that the prior art taught the cojoining of ethanol and ranitidine. And, when Glaxo requested reconsideration of its application, Glaxo acknowledged that ethanol had previously been used in pharmaceutical compositions as a solvent or preservative against bacterial contamination. Viewed in this light, Pharmadyne has failed to establish the materiality of the Tagamet reference.

Id. at 310-311.

Teva simply cannot provide any evidence, much less clear and convincing evidence, to support its vague and specious allegations or to alter the *Pharmadyne* court's conclusions. The Tagamet solution, either alone or in combination with any other reference, does not disclose the claimed invention of the '249 patent. *See id.* at 301. The Tagamet solution does not disclose or suggest that ethanol could be used to enhance the stability of ranitidine in an aqueous formulation for oral administration. *See id.* (*See also* Anderson Rebuttal Rpt. ¶ 56).

Moreover, although both Tagamet and ranitidine are used to treat ulcer-type ailments, they are chemically different. *See id.* (relying on testimony from Dr. Wray that "there are marked differences between the '249 patent and Tagamet"). (*See also* Wray Tr.[12] 4812-13, Langer Decl., Ex. 15; Wood Tr.[13] 74-75, Langer Decl., Ex. 2). Tagamet's active ingredient is cimetidine, not ranitidine. *See id.* (*See also* Wray Tr. 501-02, Langer Decl., Ex. 15; Anderson Rebuttal Rpt. ¶ 56; Wood Tr. 73-74, Langer Decl., Ex. 2). Cimetidine is a guanadine, not an enamine, like ranitidine. *See Pharmadyne*, 32 F. Supp. 2d at 301. (*See also* Wray Tr. 4813, Langer Decl., Ex. 15). The two chemical compounds have different ring structures in addition to differences in their side chains. *See id.* (stating that "the two chemical compounds are

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12 "Wray Tr." refers to the trial testimony of Dr. Paul Wray in the *Pharmadyne* case.

13 "Wood Tr." refers to the trial testimony of Dr. John Wood in the *Pharmadyne* case.

chemically different"). (*See also* Wray Tr. 4813, Langer Decl., Ex. 15). Further, cimetidine causes side-effects in patients that are not presented by patients taking a ranitidine product, presumptively due, at least in part, to the chemical differences between the two compounds. *See id.* ("Furthermore, cimetidine causes side-effects in patients that are not presented by patients taking a ranitidine product .... [T]his is due at least in part to the chemical differences between the two compounds."). (*See also* Wood Tr. 73, Langer Decl., Ex. 2). Given that cimetidine and ranitidine are different chemical compounds and that the Tagamet solution does not disclose or suggest the claimed invention of the '249 patent, the Tagamet solution is not material to the claims of the '249 patent. *See Pharmadyne*, 32 F. Supp. 2d at 301, 310 ("In the absence of evidence showing similarities between the two compounds, I cannot conclude that the '249 patent would have been obvious from the PDR [Tagamet] reference alone, or in combination with any of the other references.").

Even if the Tagamet solution is at all material (it is not), at most, it is cumulative of the prior art references already reviewed and considered by the Examiner. *See id.* at 302 ("Pharmadyne did not present any prior art more relevant than that reviewed by the PTO."), 310. The Examiner reviewed, among other references, two Chemical Abstracts provided by Glaxo, which referenced the applicable drug substance, ranitidine, and the Examiner rejected all of the originally-filed claims numerous times on the ground that the prior art taught the cojoining of ethanol and ranitidine. *See id.* at 311. (*See also* '249 File History at G000264-65, G000272, G000132, G000161, G000171, Langer Decl., Ex. 10).

Further, not only is the Tagamet solution not material and, at most, cumulative, Teva cannot prove by clear and convincing evidence that Glaxo and/or its representatives withheld knowledge regarding the Tagamet solution with the intent to mislead the PTO. When Glaxo

requested reconsideration of the claims in its application, Glaxo acknowledged that ethanol had previously been used in pharmaceutical compositions as a solvent or preservative against bacterial contamination. *See id.* (*See also* '249 File History at G000205, Langer Decl. Ex. 10).

Accordingly, Glaxo is entitled to summary judgment dismissing Teva USA's defense and corresponding counterclaim and Teva Israel's defense alleging that Glaxo and/or its representatives committed inequitable conduct by "knowingly withh[olding] knowledge of a Tagamet solution containing ethanol from the [PTO]."

2. Teva Cannot Prove By Clear And Convincing Evidence That Glaxo Knowingly Withheld Stability Data From The PTO During The Prosecution Of The '249 Patent With The Intent To Mislead The PTO

Teva alleges that Glaxo and/or its agents (including Dr. Hempenstall) knowingly withheld material stability data from the PTO during the prosecution of the '249 patent with the intent to mislead the PTO. The *Pharmadyne* court rejected this same allegation[14], concluding that Dr. Hempenstall did not commit inequitable conduct. *Pharmadyne*, 32 F. Supp. 2d at 313. The *Pharmadyne* court explained that, although "[t]here is no question that Glaxo should have provided the PTO with all of the experimental data from both the United Kingdom and United States studies[,] . . . . Glaxo's conduct in its totality does not 'manifest a sufficient culpable state of mind' to conclude that Dr. Hempenstall had an intent to deceive the PTO." *Id.* at 312. The

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[14] In the *Pharmadyne* case, Pharmadyne alleged that "Dr. Hempenstall intentionally withheld and misrepresented stability data in his declaration." 32 F. Supp. 2d at 311. Pharmadyne alleged that "Dr. Hempenstall reported only favorable data and should have included all of the data available to him." *Id.* Unlike Teva's vague and specious allegations, however, Pharmadyne asserted that "Dr. Hempenstall intentionally withheld all of the stability data from the United Kingdom studies and the 20°C data from the United States stability studies because that data demonstrated that the non-ethanol formulations had greater stability than the ethanol formulations." *Id.* Pharmadyne also "challenged Dr. Hempenstall's inclusion of the

(Cont'd)

Pharmadyne court went on to explain: "Although I am troubled by Glaxo's failure to present all of the statistical data to the PTO, Dr. Hempenstall offered plausible explanations for limiting the data in his declaration. Moreover, [Pharmadyne's expert witness] Dr. Carstensen's testimony tends to lend credence to Dr. Hempenstall's decision." *Id.* The *Pharmadyne* court, considering and addressing all of the stability data alleged by Pharmadyne to have been improperly excluded or included, reached the following conclusion:

> I am persuaded that Dr. Hempenstall's recollection is reliable. There is no evidence that Dr. Hempenstall acted for any reason other than the reasons he stated. Pharmadyne essentially has asked the Court to find the requisite intent and materiality for inequitable conduct by Dr. Hempenstall in the exclusion of certain data from his declaration. Dr. Hempenstall excluded both favorable and unfavorable data and presented bona fide reasons for his decision to include and exclude data. Accordingly, I do not find inequitable conduct by Dr. Hempenstall.

Id. at 313.

Teva simply cannot provide any evidence, much less clear and convincing evidence, to prove its vague and specious claims or to alter the *Pharmadyne* court's conclusions. All the factual evidence relating to the preparation and submission of the Hempenstall Declaration to the PTO was properly before the *Pharmadyne* court. This included, most importantly, Dr. Hempenstall's live trial testimony that consisted of not only cross-examination by Pharmadyne's counsel, but a thorough examination by the *Pharmadyne* court itself. (Hempenstall Tr. 4334-39, Langer Decl., Ex. 16). Through this live trial testimony, the *Pharmadyne* court assessed Dr. Hempenstall's demeanor and concluded that Dr. Hempenstall

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37°C data in his declaration, on the basis that the data had not been properly analyzed and, therefore, was unreliable." *Id.*

was credible and reliable and that he had not committed inequitable conduct. *Pharmadyne*, 32 F. Supp. 2d at 313.

To overcome the prior art, the Examiner directed Glaxo to demonstrate that the use of ethanol in an aqueous formulation for oral administration has the claimed effect of enhancing the stability of ranitidine. *See id.* at 311. (*See also* '249 File History at G000161, G000200 ("It has not been demonstrated in the record, by means of experimental data, that the applicant's invention produces any unexpected results. The disclosure, as presented, is insufficient to overcome the prior art without the aid of experimental data to show a definite improvement over the GB patent [the '820 patent]," Langer Decl., Ex. 10). Dr. Hempenstall provided the supporting data in the Hempenstall Declaration that Glaxo filed with the PTO. Before Dr. Hempenstall prepared the Hempenstall Declaration, he asked Glaxo's Statistics Department for statistical analyses of the comparative studies that Glaxo had conducted on ethanol and non-ethanol formulations in the United States and the United Kingdom to determine whether the addition of ethanol to an aqueous formulation for oral administration containing the active ingredient ranitidine resulted in a statistically significant improvement in shelf-life. *See id.* at 312. (*See also* Hempenstall Tr. 4245-49, Langer Decl. Ex. 16; May 15, 1990 Elahi Report at G026932-950, Langer Decl., Ex. 17). Dr. Hempenstall used his experience and sound professional judgment in deciding what data was appropriate, fair and sufficient and what data was inappropriate, unreliable or unnecessary to include in the Hempenstall Declaration. *See id.* at 312-313. (*See also* Hempenstall Tr. 4249-61, 4280, 4294, 4334-4339, Langer Decl., Ex. 16; '249 File History at G000208-211, Langer Decl., Ex. 10; Anderson Rebuttal Rpt. ¶¶ 37-39). Teva cannot prove otherwise, and certainly cannot provide the requisite clear and convincing evidence.

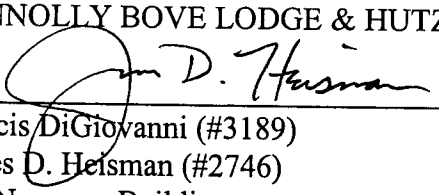
Accordingly, Glaxo is entitled to summary judgment dismissing Teva USA's defense and corresponding counterclaim and Teva Israel's defense concerning their allegations that Glaxo and/or its representatives knowingly withheld material stability data from the PTO during the prosecution of the '249 patent with the intent to mislead or deceive the PTO.

V. CONCLUSION

For the reasons set forth above, Glaxo respectfully submits that it is entitled to entry of summary judgment in its favor dismissing Teva USA's Third Affirmative Defense and corresponding counterclaim (Count III) and Teva Israel's Third and Fourth Affirmative Defenses.

Dated: June 30, 2006

CONNOLLY BOVE LODGE & HUTZ LLP



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UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on June 30 2006, I electronically filed **PLAINTIFF GLAXO'S MOTION FOR SUMMARY JUDGMENT DISMISSING DEFENDANTS' AFFIRMATIVE DEFENSES AND CORRESPONDING COUNTERCLAIM ALLEGING INEQUITABLE CONDUCT DURING THE PROSECUTION OF U.S. PATENT NO. 5,068,249** with the Clerk of Court using CM/ECF which will send notification of such filing and we will hand deliver such filing to the following:

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EXHIBIT A

Westlaw.

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2004 WL 232725 (S.D.N.Y.)
(Cite as: Not Reported in F.Supp.2d)

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,S.D. New York.

AT & T CORP., Plaintiff,

v.

MICROSOFT CORPORATION, Defendant.

No. 01 Civ.4872 WHP.

Feb. 9, 2004.

Background: Patent owner sued software company, alleging that certain of the company's products containing speech codecs infringed the patent.

Holding: On the owner's motion for partial summary judgment on the company's affirmative defense and counterclaim of inequitable conduct, the District Court, Pauley, J., held that company failed to prove that a paper purportedly constituting material prior art was withheld from the United States Patent and Trademark Office (PTO) examiner with intentional deception.

Motion granted.

West Headnotes

Patents 291 97

291 Patents
291IV Applications and Proceedings Thereon
291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases
Software company whose products containing speech codecs allegedly infringed a patent failed to prove that a paper purportedly constituting material prior art was withheld from the United States Patent and Trademark Office (PTO) examiner with intentional deception, thus precluding the company from establishing an affirmative defense and counterclaim of inequitable conduct; at most, the company could show that the paper's co-author, who had authored over 40 articles at the time the patent was prosecuted, was negligent in not disclosing the paper to the examiner; facts surrounding the dispute supported the veracity of the patent owner's belief of non-materiality, as well as the notion that the owner was not attempting to dupe the PTO.

Patents 291 328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original Utility. Most Cited Cases

Patents 291 328(4)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(4) k. Reissue. Most Cited Cases
4,354,057, 4,472,832. Cited.

32,124, 32,580. Cited.

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Dale M. Heist, David R. Bailey, Paul B. Milcetic, Woodcock, Washburn, Kurtz, MacKiewicz & Norris LLP, Philadelphia, Pennsylvania, for Defendant.
James H. Carter, Sullivan & Cromwell, New York, NY, for Defendant.
T. Andrew Culbert, Microsoft Corporation, Redmond, WA, for Defendant.

MEMORANDUM AND ORDER

PAULEY, J.

***1** Plaintiff AT & T Corp. ("AT & T") brings this patent infringement action against Microsoft Corporation ("Microsoft"), alleging that certain of Microsoft's products containing speech codecs [FN1] infringe its United States Patent No. Reissue 32,580 (the "580 patent"). Microsoft denies infringement of the 580 patent and seeks dismissal of the complaint together with a declaratory judgment of noninfringment, invalidity and unenforceability of the 580 patent. *See AT & T Corp. v. Microsoft Corp.*, 01 Civ. 4872(WHP), 2003 WL 21459573 (S.D.N.Y.

June 24, 2003). Familiarity with this Court's prior Memoranda and Orders is presumed.[FN2]

FN1. "A speech codec is a software program that is capable of coding-converting a speech signal into a more compact code-and decoding-converting the more compact code back into a signal that sounds like the original speech signal." Amended Complaint ("Am.Compl.") ¶ 14.

FN2. On June 24, 2003, this Court issued a Memorandum and Order construing certain claims in the 580 patent. *AT & T Corp. v. Microsoft Corp.*, 01 Civ. 4872(WHP), 2003 WL 21459573 (S.D.N.Y. June 24, 2003). On September 3, 2003, this Court issued an Order amending its construction of the term "representative." *AT & T Corp. v. Microsoft Corp.*, 01 Civ. 4872(WHP) (S.D.N.Y. Sept. 3, 2003). Additionally, on November 5, 2003, this Court issued a Memorandum and Order granting Microsoft's motion for partial summary judgment limiting damages pursuant to the patent marking statute, 35 U.S.C. § 287(a). *AT & T Corp. v. Microsoft Corp.*, 290 F.Supp.2d 409 (S.D.N.Y.2003). On February 2, 2004, this Court granted partial summary judgment prohibiting Microsoft from asserting the defenses of equitable estoppel and implied license at trial. *AT & T Corp. v. Microsoft Corp.*, 01 CV 4872(WHP), 2004 WL 188078 (S.D.N.Y. Feb. 2, 2004).

Currently before this Court is AT & T's motion for partial summary judgment on Microsoft's affirmative defense and counterclaim of inequitable conduct. For the reasons set forth below, AT & T's motion for partial summary judgment is granted.

BACKGROUND

Microsoft's inequitable conduct defense and counterclaim concerns whether the inventors of the 580 patent, Dr. Bishnu S. Atal and Mr. Joel R. Remde, and the in-house patent attorney who prosecuted that application, Jack S. Cubert, Esq., intentionally failed to disclose material prior art to the United States Patent and Trademark Office (the "PTO") during prosecution of the 580 patent. Specifically, Microsoft claims that AT & T should have disclosed to the PTO a 1980 paper co-authored by Dr. Atal and Dr. Manfred R. Schroeder entitled "Improved Quantizer for Adaptive Coding of Speech Signals at Low Bit Rates" (the "1980 Paper").[FN3] (AT & T Ex. 1, Ex. 3 at 35-36.) Microsoft contends that the 1980 Paper anticipated one or more of the 580 patent claims, making it material, and raising an inference of intent to deceive the PTO. The facts underlying this motion are not in dispute.[FN4]

FN3. In another motion for summary judgment before this Court, AT & T and Microsoft dispute whether the 1980 Paper qualifies as prior art. AT & T concedes, for purposes of this summary judgment motion only, that the 1980 Paper qualifies as prior art under 35 U.S.C. § 102(b). (AT & T Br. at 2.)

FN4. While Microsoft did not file a 56.1 Statement, it included a "Counterstatement of Material Facts" in its opposition memorandum. (MS Opp. at 5.) Microsoft's Counterstatement refers to numerous paragraphs of AT & T's 56.1 Statement as well as certain exhibits attached to AT & T's motion for summary judgment. Although procedurally deficient, this Court liberally construes portions of Microsoft's Counterstatement of Material Facts as its 56.1 Statement, where those factual assertions are supported by citation to exhibits. *See* Local Rule 56.1.

A. *Prosecution History of AT & T's 580 and 832 Patents*

The 580 patent at issue in this litigation is a reissue of U.S. Patent No. 4,472,832 (the "832 patent"). The 832 patent contains 39 claims. *See AT & T*, 2003 WL 21459573, at *1. On December 1, 1981, AT & T filed an application for the 832 patent on behalf of the inventors, Dr. Atal and Mr. Remde. (AT & T 56.1 Stmt. ¶ 1; AT & T Ex. 4 at ATT 161-ID.) Jack S. Cubert, Esq. prosecuted the 832 patent and PTO Examiner E.S. Matt Kemeny ("Examiner Kemeny") examined that application. (AT & T 56.1 Stmt. ¶¶ 2, 3; AT & T Ex. 4 at ATT 161-ID, 211-ID.) AT & T did not disclose the 1980 Paper to the PTO during the prosecution of the 832 patent, and the PTO did not cite to the 1980 Paper during the prosecution of the 832 patent. (AT & T 56.1 Stmt. ¶ ¶ 4-5; AT & T Ex. 4 at ATT 227-ID.) The PTO issued the 832 patent on September 18, 1984. (AT & T Ex. 4 at ATT 161-ID.)

On September 18, 1986, AT & T filed a reissue application, which was also prosecuted by Cubert and examined by Examiner Kemeny. (AT & T Ex. 6 at ATT3-ID.) The 580 patent left the original 39 claims unaltered and added claims 40-43. *See AT & T, 2003 WL 21459573*, at *1. AT & T did not disclose, and the PTO did not cite to any additional references other than the ones disclosed during prosecution of the 832 patent. (AT & T Ex. 6 at ATT 3-ID; AT & T 56.1 Stmt. at ¶ 11.) The PTO issued the 580 patent on January 19, 1988. (AT & T Ex. 6 at ATT 3-ID.)

B. *The 1980 Paper and the 057 and 124 Patents*

2 In 1980, Drs. Atal and Schroeder co-authored the 1980 Paper, which they presented at the Institute of Electrical and Electronics Engineers, Acoustics, Speech and Signal Society conference on April 9-11, 1980. (AT & T Ex. 1 at MSATT 34539; Deposition of Bishnu S. Atal, Ph.D., dated March 5, 2003 ("Atal Dep.") at 226-28.) On April 8, 1980, one day before the conference, AT & T filed a patent application on behalf of Dr. Atal based on the subject matter of the 1980 Paper. (AT & T Exs. 1, 8; Atal Dep. at 226-28.) On October 12, 1982, the PTO approved this application and issued U.S. Patent No. 4,354,057 (the "057 patent"). Like the 832 and 580 patents, Cubert prosecuted the 057 patent for AT & T and Examiner Kemeny examined the application for the PTO. (AT & T Ex. 8.)

On October 12, 1984, AT & T filed a reissue application for the 057 patent. That application was also prosecuted by Cubert and examined by Examiner Kemeny. The PTO issued U.S. Patent No. Reissue 32,124 (the "124 patent") on April 22, 1986, five months before AT & T filed its 580 reissue application. The parties refer to the 124 and 057 patents as the "Center Clipping Patents."

Thus, Cubert shepherded all four of the AT & T applications through prosecution on behalf of AT & T and PTO Examiner Kemeny examined each of the patent applications on an ongoing basis from April 1980 through January 1988.

DISCUSSION

I. *Summary Judgment Standard*

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c); *accord Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); *Anderson v.. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The burden of demonstrating the absence of any genuine dispute as to a material fact rests with the moving party. *See, e.g., Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970); *Grady v. Affiliated Cent., Inc.*, 130 F.3d 553, 559 (2d Cir.1997). The movant may meet this burden by demonstrating a lack of evidence to support the nonmovant's case on a material issue on which the nonmovant has the burden of proof. *Celotex*, 477 U.S. at 323.

To defeat a summary judgment motion, the nonmoving party must do "more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). Indeed, the nonmoving party must "set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e); *accord Matsushita Elec.*, 475 U.S. at 587. In evaluating the record to determine whether there is a genuine issue as to any material fact, the "evidence of the nonmovant is to be believed and all justifiable inferences are to be drawn in his favor." *Liberty Lobby*, 477 U.S. at 255.

3 "Although the premises of inequitable conduct require findings based on all the evidence, a procedure that may preclude summary determination, a motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail ." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed.Cir.1998) (citation omitted); *accord Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189-90 (Fed.Cir.1993) (noting that inequitable conduct defense is not amenable to summary judgment if "the facts of materiality or intent are reasonably disputed").

II. *Applicable Legal Standards*

Patent applicants are required to prosecute applications with "candor, good faith, and honesty." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer,*

Inc., 326 F.3d 1226, 1233 (Fed.Cir.2003); *see also* 37 C.F.R. § 1.175(a)(7) (1986) (duty of candor applies throughout the prosecution of the patent). An otherwise valid patent may be rendered unenforceable by virtue of inequitable conduct committed during the prosecution of the patent application before the PTO. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1556 (Fed.Cir.1995). To establish a defense of inequitable conduct, Microsoft must prove: (1) that the "applicant failed to disclose material information to the PTO"; and (2) that the applicant "intended thereby to mislead or deceive the patent examiner into granting the patent." *ATD Corp.*, 159 F.3d at 546; *accord Key Pharm. v. Hercon Labs. Corp.*, 161 F.3d 709, 719 (Fed.Cir.1998). The burden is on Microsoft to establish materiality and inequitable conduct by clear and convincing evidence. *Life Techs v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326-27 (Fed.Cir.2000); *see also Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed.Cir.2002) (affirming district court's grant of summary judgment of no inequitable conduct where accused infringer could not prove materiality and intent by clear and convincing evidence). Inequitable conduct must be determined by this Court at trial, unless the parties otherwise consent to submit it to the jury. *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 876 (Fed.Cir.1988) (en banc). AT & T does not consent to submit this issue to the jury. (AT & T Br. at 11.)

A document is material "if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed.Cir.1998) (internal quotations omitted). A document is immaterial when it is "merely cumulative of references that were already before the examiner." *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 224 F.3d 1365, 1378 (Fed.Cir.2001); *accord Baxter Int'l*, 149 F.3d at 1327. Although the legal standard for determining whether a prior art reference is "material" was amended in 1992, the Federal Circuit continues to apply the "reasonable examiner" standard of 37 C.F.R. § 1.56, in effect from 1977 through 1992, to patent applications prosecuted within that time period. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed.Cir.2003); *Li Second Family Ltd. Pshp. v. Toshiba Corp.*, 231 F.3d 1373, 1379-80, 1380 n. 4 (Fed.Cir.2000); *see also Purdue Pharma L.P. v. Endo Pharms. Inc.*, No. 00 Civ. 8029(SHS), 2004 WL 26523, at *20 (S.D.N.Y. Jan.5, 2004) (providing a comprehensive history of the materiality standard). This Court notes that the 1992 amendment "was not intended to constitute a significant substantive break with the previous standard." *Hoffman La-Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n. 2 (Fed.Cir.2003).

***4** "Materiality does not presume intent," however, and Microsoft must separately prove deceptive intent by clear and convincing evidence. *Braun Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 822 (Fed.Cir.1992) (quotation omitted); *accord Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed.Cir.2003) (affirming finding of no inequitable conduct where record "was bereft of evidence of intentional deception"); *Gambro Lundia AB v.. Baxter Healthcare Corp.*, 110 F.3d 1573, 1581-82 (Fed.Cir.1997). Indeed, "a mere showing that references having some degree of materiality were not disclosed does not establish inequitable conduct." *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed.Cir.1991). As direct evidence of intent is "rarely available in instances of inequitable conduct," intent may be inferred from circumstantial evidence. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed.Cir.1997); *accord LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed.Cir.1992). However, negligence in failing to disclose a reference "can support an inference of intent only when, 'viewed in the light of all the evidence, including evidence of good faith,' the conduct is culpable enough 'to require a finding of intent to deceive." ' *Halliburton*, 925 F.2d at 1443 (quoting *Kingsdown*, 863 F.2d at 876).

Second, "[a]fter threshold findings of materiality and intent have been established by clear and convincing evidence, the court must weigh them to determine" "whether the applicant's conduct is *so culpable* that the patent should be held unenforceable." *Ulead Sys., Inc. v. Lex Computer & Mgm't Corp.*, 351 F.3d 1139, 1144 (Fed.Cir.2003); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed.Cir.2003) (emphasis in original); *accord Glaverbel Societe Anonyme*, 45 F.3d at 1558 ("All of the evidence, including evidence tending to show good faith, must establish sufficient culpability to establish both materiality and intent."). "As a general principle, materiality and intent are balanced-a lesser quantum of evidence is necessary when the omission or misrepresentation is highly material, and vice versa. At the same time, however, there must be some showing of intent to be balanced." *Amgen*, 314 F.3d at 1358 (citing *GFI*, 265 F.3d at 1273). Indeed, a

court cannot find "inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO." *Amgen*, 314 F.3d at 1358 (citing *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed.Cir.2002)).

Finally, this Court notes that "[t]he Federal Circuit has long decried the use of charging inequitable conduct in patent litigation ." *TM Patents, L.P. v. Int'l Bus. Mach. Corp.*, 121 F.Supp.2d 349, 372 (S.D.N.Y.2000); *accord* *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed.Cir.1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed.Cir.1987) ("Inequitable conduct is not, or should not be, a magic incantation to be asserted against every patentee."); *Chiron Corp. v. Abbott Labs.*, 156 F.R.D. 219, 221 (N.D.Cal.1994) (finding inequitable conduct is often used as a delay tactic, a tactic to obfuscate the issues before the court, or a settlement tactic).

III. *Merits*

***5** AT & T argues that it is entitled to partial summary judgment on Microsoft's inequitable conduct defense and counterclaim because Microsoft cannot prove by clear and convincing evidence that 1980 Paper was material or withheld from the PTO Examiner with intentional deception. This Court agrees.

Even if Microsoft could show that the 1980 Paper was material to the prosecution of the 580 patent, it cannot show an intent to deceive by clear and convincing evidence. *See* *Amgen*, 314 F.3d at 1358 (affirming finding of no inequitable conduct where defendant could not prove intent by clear and convincing evidence); *GFI*, 265 F.3d at 1273 ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct."); *Halliburton*, 925 F.2d at 1442 ("Materiality of an undisclosed reference does not presume an intent to deceive."). At most, Microsoft can show by clear and convincing evidence that Dr. Atal, the author of over forty articles at the time AT & T prosecuted the 580 patent, was negligent in not disclosing the 1980 Paper to the Examiner. It is well-established, however, that negligence, and even gross negligence, is insufficient to support a finding of intent to deceive, especially when rebutted by evidence of good faith. *See, e.g.*, *Ulead Sys.*, 351 F.3d at 1145-46; *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342-43 (Fed.Cir.2003); *Kingsdown*, 863 F.2d at 876.

Microsoft relies solely on Dr. Atal's knowledge of his own article, the 1980 Paper, to establish his intent to deceive the PTO. Specifically, Microsoft argues that the 1980 Paper was so material that its nondisclosure justifies an inference of intent to deceive. (MS Opp. at 15.) The Federal Circuit has expressly rejected Microsoft's argument. *See, e.g.*, *Allen Eng'g*, 299 F.3d at 1351-52; *Braun*, 975 F.2d at 822. Indeed, "[i]ntent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 694 (Fed.Cir.2001) (affirming finding of no intent to deceive where defendant argued that inventors failed to disclose highly relevant prior art articles) (citing *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed.Cir.1996)); *accord* *Glaverbel Societe Anonyme*, 45 F.3d at 1557-58 (Fed.Cir.1995) (affirming finding of no intent to deceive where patentee failed to disclose allegedly material prior art, but believed such prior art related to a different process than the patent in suit); *Halliburton*, 925 F.2d at 1442 ("[A] mere showing that references having some degree of materiality were not disclosed does not establish inequitable conduct."). Indeed, the undisputed evidence shows that the patentees acted in good faith and unequivocally believed that the 1980 Paper was irrelevant to the prosecution of the 580 patent. *See* *Halliburton*, 925 F.2d at 1443 (holding that good faith must be taken into account in determining whether nondisclosure constitutes conduct culpable enough to require a finding of intent to deceive); *Glaverbel Societe Anonyme*, 45 F.3d at 1558 ("All of the evidence, including evidence tending to show good faith, must establish sufficient culpability to establish both materiality and intent."). Dr. Atal repeatedly testified at his deposition that he was aware of the 1980 Paper, but did not disclose it because it was "completely unconnected" and involved "an entirely different topic" than the 832 and 580 patents. (Atal Dep. at 268, 291-92.) Additionally, Remde testified that he was not aware of any relevant prior art to give to the PTO. (Deposition of Joel Remde, dated August 13, 2002 ("Remde Dep.") at 79 ("I was not aware of any relevant material, so I didn't produce any material").) Further, Cubert, who left AT & T in 1990, also testified that he had no recollection of prosecuting the 580, 832, or the Center Clipping patents approximately two decades ago. (Deposition of Jack

Cubert, Esq., dated October 29, 2003 ("Cubert Dep.") at 40-42, 53-54.) Cubert ceased working for AT & T's speech processing group in 1987 and took on responsibilities involving a "completely different subject matter." (Cubert Dep. at 54.)

*6 It is well-established that a patent applicant's mere awareness of nondisclosed prior art does not alone establish an intent to deceive. *See, e.g., Halliburton,* 925 F.2d at 1443 (finding patentee's assertion of no intent to deceive "objectively reasonable" despite awareness of the nondisclosed references, where patentee did not consider the references material); *Glaverbel Societe Anonyme,* 45 F.3d at 1557-58 (same); *Braun,* 975 F.2d at 822 (lack of knowledge of materiality can rebut an inequitable conduct allegation). Accordingly, Microsoft cannot establish an intent to deceive the PTO by clear and convincing evidence based solely on the patentee's awareness of the 1980 Paper.

Notably, the facts surrounding this dispute support the veracity of the patentee's belief of non-materiality, as well as the notion that AT & T was not attempting to dupe the PTO. AT & T prosecuted the 580 patent nearly contemporaneously with its prosecution of the Center Clipping patents, which are based on the subject matter of the 1980 Paper.[FN5] AT & T knew that PTO Examiner Kemeny was examining both the 580 and the Center Clipping patents. (AT & T 56.1 Stmt. § 16.) Because the patentees knew that Examiner Kemeny had actual knowledge of the 1980 Paper's subject matter, there was a disincentive to deceive the PTO through nondisclosure during the prosecution of the 580 patent. "[A] patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner." *Halliburton,* 925 F.2d at 1440 (reversing finding of inequitable conduct where patentee acknowledged that it was aware of withheld references but did not consider them material); *accord Mentor H/S,* 244 F.3d at 1365 ("[M]ere knowledge of [an undisclosed, cumulative] reference ... is not an indication of an intent to deceive.")

FN5. Indeed, AT & T filed the 057 patent on behalf of Dr. Atal one day before he presented it at the April 1980 conference. (Atal Dep. at 226-27.)

Besides its argument that intent may be inferred from materiality, Microsoft submits no other basis or evidence supporting an inference that the patentees had an intent to deceive the PTO by nondisclosure of the 1980 Paper. (MS Opp. 13-16.)

Finally, Microsoft advances a meritless argument that AT & T "continues to hide behind the attorney-client privilege with respect to communications between the inventor and his patent attorney." (MS Br. at 17.) On September 23, 2003, this Court denied Microsoft's request to discover privileged documents concerning Dr. Atal's 1986 reissue declaration, including certain documents that Microsoft contends might have "confirmed or refuted Dr. Atal's ... good faith in failing to submit the 1980 paper." (MS Br. at 17; Transcript of Order, dated September 23, 2003 ("9/23 Tr.") at 1-7.) Microsoft attempts to use this Court's Order as a vehicle to argue that "the record is devoid of any evidence of good faith." (MS Br. at 17-18.) First, the burden is on Microsoft to prove deceptive intent by clear and convincing evidence, and not on AT & T to prove good faith. *See Mentor H/S,* 244 F.3d at 1377 (noting that the burden is on the defendant to prove the defense of inequitable conduct by clear and convincing evidence); *CMFT,* 349 F.3d at 1342-43 (same, holding that the patentee's conduct must indicate sufficient culpability to require a finding of intent to deceive, even when taking into account all good faith evidence).

*7 Second, Microsoft's argument implicitly suggests that AT & T has asserted the attorney-client privilege to shield evidence of bad faith-an assertion that is completely devoid of any support. It is still the case today, as it was when this Court issued its September 23, 2003 ruling (9/23 Tr. at 6-7), that Microsoft has not submitted any evidence even hinting at the patentees' fraudulent intent.

In conclusion, based on the undisputed facts, Microsoft cannot establish inequitable conduct by clear and convincing evidence because it failed to show that the patentees withheld the 1980 Paper with an intent to deceive the PTO, or that their conduct was "so culpable" as to warrant application of the defense.

CONCLUSION

For the reasons set forth above, AT & T's motion for partial summary judgment on Microsoft's affirmative defense and counterclaim of inequitable conduct is granted and Microsoft is prohibited from asserting it at trial.

S.D.N.Y.,2004.

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Not Reported in F.Supp.2d, 2004 WL 232725 (S.D.N.Y.)

Briefs and Other Related Documents (Back to top)

- 2004 WL 3545811 () Microsoft's Opposition to AT&T's Motion Inlimine to Exclude Testimony from Eugene Ericksen and ""Evidence" or Argument About Usage of the Accused Products Opposition to AT&T's Motion in Limine No. 2) (Feb. 9, 2004) Original Image of this Document with Appendix (PDF)
- 2004 WL 3545812 () Declaration of Nathaniel Polish. Ph.D. (Feb. 6, 2004) Original Image of this Document with Appendix (PDF)
- 2004 WL 3545813 () Jeclaration of Nikil S. Jayant, Ph.D. (Feb. 6, 2004) Original Image of this Document (PDF)
- 2004 WL 3545810 () Motion in Limine #7 Memorandum in Support of Microsoft's Motion in Limine to Exclude Certain Aspects of AT&T's Damages Claim Redacted Version (Jan. 26, 2004) Original Image of this Document with Appendix (PDF)
- 2004 WL 3556954 () Motion In Limine #1 (Jan. 26, 2004) Original Image of this Document (PDF)
- 2003 WL 24163224 () Redacted Version Microsoft's Reply Memorandum in Support of its Motion for Partial Summary Judgment of Invalidity of Claims 40-43 of U.S. Patent No. Re 32.580 (Dec. 8, 2003) Original Image of this Document (PDF)
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- 2003 WL 24163220 () Statement of Material Facts in Support of AT&T Corp.'s Motion for Partial Summary Judgment to Dismiss Microsoft Corporation's Affirmative Defense and Counterclaim of Inequitable Conduct (Nov. 10, 2003) Original Image of this Document (PDF)
- 2003 WL 24163221 () Microsoft's Statement of Material Facts in Support of Microsoft's Motion for Summary Judgment of Non-Infringement of U.S. Patent No. Re 32,580 (Nov. 10, 2003) Original Image of this Document with Appendix (PDF)
- 2003 WL 24163219 () Declaration of Nikil S. Jayant (Nov. 7, 2003) Original Image of this Document (PDF)
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED	:	
Plaintiff,	:	Civil Action No. 04-171-KAJ
v.	:	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED	:	
Defendants.	:	

ORDER

Whereas the Court, having considered the submissions and arguments of the parties,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED, that Glaxo Group Limited's Motion for Summary Judgment Dismissing Defendants' Inequitable Conduct defense relating to U.S. Patent No. 5,068,249 is GRANTED for the reasons set forth in Glaxo Group Limited's moving papers.

_____
United States District Court Judge